IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,)
Plaintiff,)
v.) Civil Action No. 23-975-RGA-SRF
LIQUIDA TECHNOLOGIES, INC.,)
Defendant.)

MEMORANDUM ORDER

At Wilmington this **12th** day of **November**, **2024**, the court having considered the parties' letter submissions and associated filings (D.I. 179; D.I. 180; D.I. 181; D.I. 184; D.I. 185), IT IS ORDERED that the pending motion at D.I. 151 is addressed as follows:

DEFENDANT'S ISSUES

1. Defendant's motion for a unilateral extension of the fact and expert discovery deadlines by one month is DENIED without prejudice. "A schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4); Lehman Bros. Holdings v. Gateway Funding Diversified Mortg. Servs., L.P., 785 F.3d 96, 102 (3d Cir. 2015). To satisfy the good cause standard, the movant must show that, "despite its own diligent efforts, scheduling deadlines cannot be met." Siemens Med. Sols. USA, Inc. v. Humedica, Inc., C.A. No. 14-880-LPS-CJB, 2015 WL 1738186, at *1 (D. Del. Apr. 8, 2015). The analysis turns on the "diligence of the movant, and not on prejudice to the non-moving party." Id. (quoting Cloud Farm Assocs. L.P. v. Volkswagen Grp. of Am. Inc., C.A. No. 10-502-LPS, 2012 WL 3069390, at *2 (D. Del. July 27, 2012)).

- 2. Defendant cites two late or ongoing document productions and one third-party deposition that has not yet been scheduled to justify its request for a unilateral one-month extension of the November 13, 2024 fact discovery deadline. (D.I. 179 at 2) As a preliminary matter, Defendant cites no case authority to support a request for extension of the fact and expert discovery deadlines for itself, while maintaining the existing deadlines for Plaintiff. Moreover, the record before the court does not support Defendant's position that an extension of the case schedule is necessary to accommodate the remaining fact discovery. *See McGoveran v. Amazon Web Servs., Inc.*, C.A. No. 20-1399-SB, 2024 WL 4533598, at *2 (D. Del. Oct. 18, 2024) (declining to "extend discovery wholesale" where the defendant failed to identify "particular depositions that hinge[] on late-breaking documents and reasons why they could not be completed by the deadline.").
- 3. Defendant first argues that Plaintiff's belated production of custodial documents from inventor Peter Smith after the deadline for substantial completion of document production warrants a unilateral extension of the fact and expert discovery deadlines. (D.I. 179 at 2)

 Defendant represents that Smith's custodial documents were produced by October 23, 2024, and his deposition was rescheduled for the last day of fact discovery on November 13, 2024. (*Id.*; Ex. 17) Defendant does not suggest that it has insufficient time to prepare for Smith's rescheduled deposition within the fact discovery period. Instead, Defendant's argument focuses on unspecified prejudice resulting from the need to reschedule Smith's deposition caused by the belated document production. (*Id.*) Defendant has not shown that the scheduling order deadlines cannot be met, and its focus on alleged prejudice does not support its good cause argument. *See Siemens*, 2015 WL 1738186, at *1 (explaining that satisfaction of the good cause requirement depends on the diligence of the movant, and not on prejudice to the non-moving party).

- 4. Next, Defendant contends that it was prejudiced by Plaintiff's incomplete document production in response to several Requests for Production. (D.I. 179 at 2) This alleged deficiency was raised for the first time on October 18, 2024, one day after the parties filed their joint motion requesting a teleconference, and it is therefore not ripe for the court's review. (Id., Ex. 18 at 2-3; D.I. 151) Defendant ties this argument to its position that Plaintiff withheld communications involving Drs. Rajan and Rajeev Saggar. (Id. at 2) But Defendant's own submission confirms that documents from Dr. Rajan Saggar were produced on October 28 in response to a third-party subpoena. (D.I. 179, Ex. 18 at 1) The record also confirms that counsel for Defendant represents Dr. Rajan Saggar in connection with the subpoena, and documents from Dr. Rajeev Saggar were available to Defendant in his capacity as Defendant's CMO. (Id., Ex. 19) at 1; D.I. 185, Ex. 2) Moreover, Plaintiff confirmed that it reviewed and produced all responsive communications involving both individuals that were within the custodial files. (D.I. 179, Ex. 19) at 1) Defendant has not persuasively shown that an extension of the discovery deadlines is necessary to accommodate the production and review of communications involving Drs. Rajan and Rajeev Saggar.
- 5. Finally, Defendant argues that Plaintiff has still not provided a deposition date for third party Dr. Aaron Waxman. (D.I. 179 at 2) Defendant acknowledges that other fact depositions are already scheduled to proceed after the close of fact discovery and fails to explain why the likelihood of an out-of-time deposition for Dr. Waxman requires a one-month extension of the fact discovery deadline. (*Id.*)
- 6. Defendant's motion to compel Plaintiff to respond to Interrogatory Nos. 4 and 5 is GRANTED. Defendant's Interrogatory Nos. 4 and 5 seek Plaintiff's contentions regarding the mechanism of action of treprostinil in treating pulmonary hypertension associated with

interstitial lung disease ("PH-ILD") and the priority date of asserted U.S. Patent No. 11,826,327 ("the '327 patent"), respectively. (D.I. 179 at 3; Ex. 11 at 49-51) Plaintiff argues that it responded to the interrogatories by producing documents under Rule 33(d), and the requests otherwise improperly seek expert discovery. (D.I. 185 at 3) Plaintiff has nonetheless agreed to supplement its responses to Interrogatory Nos. 4 and 5 prior to the fact discovery cutoff on November 13, 2024. (*Id.*)

7. Plaintiff shall supplement its responses to Interrogatory Nos. 4 and 5 on or before November 19, 2024. Plaintiff's supplementation shall include narrative responses to the interrogatories, consistent with case authority from this district holding that "Rule 33(d) has no place in a response to a contention interrogatory in which the requesting party is seeking to learn what the other party's position is with respect to a material issue in the case." *IOENGINE, LLC v. PayPal Holdings, Inc.*, C.A. No. 18-452-WCB, 2021 WL 12160836, at *4 (D. Del. Oct. 22, 2021). Plaintiff is not required to provide its expert opinion on the mechanism of action of inhaled treprostinil or the priority date of the '327 patent in its supplemental interrogatory responses, but the supplementation shall include a narrative response describing how the information contained in the cited documents supports Plaintiff's positions. *Id.* at *2-4; *see Blast Motion, Inc. v. Zepp Labs, Inc.*, 2016 WL 5107677, at *3 (S.D. Cal. Mar. 2, 2016) (granting motion to compel further responses to contention interrogatory regarding priority date discovery after parties had served their infringement and invalidity contentions).

¹ Although Plaintiff agreed to supplement its responses to Interrogatory Nos. 4 and 5 by the fact discovery deadline on November 13, 2024, additional time is granted due to the temporal proximity of this Memorandum Order to the fact discovery deadline.

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- 8. Defendant's motion to compel Plaintiff to provide a date for the deposition of Dr. Martine Rothblatt is DENIED without prejudice. The parties dispute whether a deposition of Dr. Martine Rothblatt, Plaintiff's CEO, is proper under the apex doctrine, which generally bars the deposition of a high-ranking official if that official "does not have first-hand knowledge of relevant information, or if there are others equally well (or better) situated to provide such information." *British Telecommc 'ns PLC v. IAC/Interactivecorp*, C.A. No. 18-366-WCB, 2020 WL 1043974, at *8 (D. Del. Mar. 4, 2020). Defendant alleges that Dr. Rothblatt's first-hand knowledge of the prior use of Tyvaso to treat PH-ILD is relevant to issues such as obviousness, prior public use, and prior sale, and Plaintiff's designated 30(b)(6) witness was not prepared to testify in detail on this subject. (D.I. 179 at 4) Plaintiff responds that Dr. Rothblatt's single public statement made to investors over six years ago is not sufficient to establish unique, first-hand knowledge of relevant information, and Plaintiff's 30(b)(6) testimony offered on the subject was sufficient. (D.I. 185 at 3-4)
- 9. The record does not support Defendant's position that Dr. Rothblatt's deposition is warranted due to her personal or unique knowledge on relevant subject matters. *See In re Jevic Holding Corp.*, 526 B.R. 547, 556 (D. Del. 2014). Defendant's own letter submission confirms that Dr. Rajan Saggar and lead investigators of the INCREASE study also had knowledge of the investigation into treating PH-ILD using inhaled treprostinil. (D.I. 179 at 4) (citing D.I. 96 at 14; D.I. 179, Ex. 15 at 89:21-93:12). Defendant argues that 30(b)(6) designee Dean Bunce was not sufficiently prepared to testify on the topic in support of its argument that the information cannot be obtained through less burdensome means. (*Id.*) But Defendant does not request a supplemental 30(b)(6) deposition to remedy the alleged deficiency. Instead, Defendant seeks to depose Dr. Rothblatt, Plaintiff's CEO. On this record, the court is not persuaded to depart from

Telecommc'ns, 2020 WL 1043974, at *8.

the general rule against permitting the deposition of a high-ranking corporate official. British

PLAINTIFF'S ISSUE

- 10. Plaintiff's motion to compel Defendant to produce documents responsive to Request for Production Nos. 11 to 15 and a witness to testify on those documents is GRANTED-IN-PART. Request for Production Nos. 11 to 15 seek launch and post-launch-related forecasts and projections for Defendant's YutrepiaTM product, including anticipated sales, revenue, profits, market share, pricing, rebates, discounts, chargebacks, promotions, and insurance coverage and listings. (D.I. 180, Ex. B) Plaintiff contends that this information is relevant to objective indicia of non-obviousness, induced and willful infringement, and damages. (*Id.* at 2-4) Defendant challenges Plaintiff's assertion of relevance and contends that the burden of producing the discovery outweighs its likely benefit. (D.I. 184)
- 11. Plaintiff's motion to compel the production of documents responsive to Request for Production Nos. 11 to 15 is GRANTED-IN-PART. On or before November 19, 2024, Defendant shall produce documents responsive to Request for Production Nos. 11 to 15, but only to the extent that the discovery requests seek sales projections and market forecasts relating to PH-ILD.² Defendant shall produce a witness to testify on the responsive documents on or before November 26, 2024. Plaintiff's motion to compel is DENIED without prejudice in all other respects.
- 12. Plaintiff has demonstrated that these forecasts and projections for Defendant's unlaunched YutrepiaTM product are relevant to a potential claim for damages.³ See Amgen Inc. v.

² "PH-ILD" is the abbreviation for pulmonary hypertension associated with interstitial lung disease. See \P 6, supra.

³ Plaintiff argues that the requested discovery is also relevant to claims for induced and willful

Zydus Pharms. (USA) Inc., 2020 WL 10140955, at *4 (D.N.J. May 22, 2020). Defendant does not deny Plaintiff's assertion that it has repeatedly threatened to launch the accused product "at risk" prior to the conclusion of this case when Plaintiff's exclusivity period expires in May of 2025. (D.I. 180 at 3; Ex. D at 2, Ex. E at 1; D.I. 184 at 3-4) Plaintiff offered to drop its damages position if Defendant agreed to stipulate that it will not launch YutrepiaTM before the end of this case, but Defendant's responsive letter does not acknowledge this proposal. (Id.) Should Defendant launch YutrepiaTM before this case concludes. Plaintiff may pursue a claim for damages against Defendant if it prevails on its infringement claims. 35 U.S.C. § 271(e)(4)(C) ("[D]amages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug[.]"); GlaxoSmithKline LLC v. Teva Pharms. USA. Inc., 7 F.4th 1320, 1341-42 (Fed. Cir. 2021). Documents such as market forecasts and sales projections are therefore discoverable. See Amgen, 2020 WL 10140955, at *4 (granting discovery on market forecasts and sales projections among other topics, i.e., product development and the estimated schedule for regulatory approval, as related to an ANDA applicant's potential at-risk launch).

13. Defendant attempts to distinguish Amgen Inc. v. Zydus Pharms. (USA) Inc. by noting that the discovery compelled by the court in that case was limited to deposition testimony

infringement and secondary considerations of non-obviousness. (D.I. 180 at 3-4) Plaintiff offers no argument or case authority establishing the relevance of the discovery to a claim for willful infringement, nor does Plaintiff describe with specificity why the requested discovery is not cumulative of the already-produced YutrepiaTM label, the new drug application, and marketing documents as they pertain to Plaintiff's claim for induced infringement. With respect to secondary considerations of non-obviousness such as the commercial success of Plaintiff's marketed drugs, Tyvaso® and Tyvaso DPI®, Plaintiff has not shown how discovery into forecasts and sales projections for the unlaunched product will inform the analysis. See AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH, C.A. No. 17-1065-MSG-RL, 2019 WL 1428361, at *2 (D. Del. Mar. 29, 2019). The requested discovery should nonetheless be produced due to its relevance to damages.

regarding market forecasts and sales projections, as opposed to document production. (D.I. 184 at 4) But this is a distinction without a difference. In *Amgen*, the court observed that the defendant had already produced analyses and projections and concluded that the plaintiff should be permitted to depose a witness on the assumptions underlying those documents. *Amgen*, 2020 WL 10140955, at *4. The court held that discovery regarding the internal development of the ANDA product, an estimated schedule for potential regulatory approval, market forecasts, and sales projections should be permitted. *Id.* The court denied the motion to compel only to the extent that the plaintiff sought discovery into the timing of a potential launch. *Id.* Here, the scope of discovery sought by Plaintiff's Request for Production Nos. 11 to 15 does not extend to specific launch plans or the timing of a potential launch for YutrepiaTM. (D.I. 180, Ex. B at 10-11) Consequently, the court's decision in *Amgen* and the cases cited therein are persuasive authority for granting Plaintiff's motion to compel the production of market forecasts and sales projections.

14. Defendant's arguments regarding burden are not persuasive. Defendant contends that Request for Production Nos. 11 to 15 are overbroad "because there are no time limits nor restrictions calling for forecasts specific to only PH-ILD," and the forecasts are speculative because YutrepiaTM has not yet launched. (D.I. 184 at 3) Defendant offers no specifics on the volume of material at issue or the amount of time it would take to review and produce the documents. Defendant does not specifically object to Plaintiff's proposed order seeking production of the material within seven days of the court's ruling. The court's ruling addresses Defendant's concern about the overbreadth of the requests by limiting the required production to sales projections and market forecasts specific to PH-ILD.

15. Conclusion. For the foregoing reasons, IT IS ORDERED that:

a. Defendant's motion for a unilateral extension of the fact and expert discovery deadlines by one month is DENIED without prejudice.

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- b. Defendant's motion to compel Plaintiff to respond to Interrogatory Nos. 4 and 5 is GRANTED. On or before November 19, 2024, Plaintiff shall supplement its responses to Interrogatory Nos. 4 and 5.
- c. Defendant's motion to compel Plaintiff to provide a date for the deposition of Dr. Martine Rothblatt is DENIED without prejudice.
- d. Plaintiff's motion to compel the production of documents responsive to Request for Production Nos. 11 to 15 is GRANTED-IN-PART. On or before November 19, 2024, Defendant shall produce documents responsive to Request for Production Nos. 11 to 15, but only to the extent that the discovery requests seek sales projections and market forecasts relating to PH-ILD. Defendant shall produce a witness to testify on the responsive documents on or before November 26, 2024. Plaintiff's motion to compel is DENIED without prejudice in all other respects.

IT IS FURTHER ORDERED that the discovery dispute teleconference scheduled for November 13, 2024 at 11:00 a.m. is CANCELLED.

16. Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties shall jointly submit a proposed redacted version by no later than November 19, 2024, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material

would "work a clearly defined and serious injury to the party seeking closure." See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., 924 F.3d 662, 672 (3d Cir. 2019) (quoting Miller v. Ind. Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within fourteen (14) days of the date the Memorandum Order issued.

17. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to four (4) pages each.

18. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, www.ded.uscourts.gov.

United States Magistrate Judge